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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,373	11/09/2001	Marguerite B. McDonald	55915 79422	1045
44777	7590	06/22/2006	EXAMINER	
W. EDWARD RAMAGE COMMERCE CENTER SUITE 1000 211 COMMERCE ST NASHVILLE, TN 37201			THALER, MICHAEL H	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/014,373	<b>Applicant(s)</b> MCDONALD, MARGUERITE B.	
	<b>Examiner</b> Michael Thaler	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 28,29,31-34 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28,31-34,39-43 and 45 is/are rejected.
- 7) ☒ Claim(s) 29 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

New claim 44 has been renumbered as claim 45 since the claim immediately preceding this claim (previously presented) is numbered claim 44.

The disclosure is objected to because of the following informalities: On page 10, line 14, "FIG. 8" is incorrect. Appropriate correction is required.

Claims 28, 31, 32, 34, 42, 43 and 45 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yaacobi et al. (6,413,245). Yaacobi et al. disclose connecting end 56, hollow spatula-like member 52, 54 including an arcuate distal section 52 having a radius of curvature of about 11.5 mm to about 14 mm as recited from col. 6 to col. 6, line 4 (which is within the disclosed range of applicant's invention of about 10 mm to about 40 mm as recited in original claim 35 and about 8 mm to about 12 mm as recited on page 16, lines 11-12 of the specification), one side (e.g. the side shown in figure 3C which faces the top of the page, noting col. 4, lines 55-57) having a plurality of apertures (described in col. 4, lines 57-58 and shown in figure 3C, for example). The Yaacobi et al. instrument is inherently capable of separating epithelium of a cornea, particularly since it can be made of a very small size as indicated in col. 4, lines 63-66. A needle formed of 19 gauge needle stock has an

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outer diameter of 1.07 mm. This is very similar in size to the dimensions of applicant's invention as recited in [00022] of applicant's specification. In fact, the width of the upper surface 104 of applicant's invention can be as large as 1 mm while the width of contact surface 102 can be as large as 1.25 mm which is larger than the diameter of the Yaacobi et al. needle. Alternatively, it would have been obvious that the Yaacobi et al. instrument is capable of separating epithelium of a cornea for this reason. As to claim 34, note col. 5, lines 39-40. As to claim 42, note col. 5, lines 66-67. As to claim 43, note col. 5, lines 52-53.

Claims 33 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaacobi et al. (6,413,245). Yaacobi et al. fail to disclose the specific claimed dimensions and number of apertures. However, Yaacobi et al. disclose that dimensions and number of apertures other than those which are listed may be used (col. 4, lines 61-62 and 64-66 and col. 8, lines 16-19). It would have been obvious to use the specific claimed dimensions and number of apertures in the Yaacobi et al. instrument for this reason.

Claims 29 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments filed April 19, 2006 have been fully considered but they are not persuasive. All of the dimensions of the Yaacobi et al. instrument including the diameter, radius of curvature and length are either within the range of applicant's instrument or very close to it. Thus, the Yaacobi et al. instrument is inherently capable of performing the corneal separation function that applicant's instrument performs. For example, a Yaacobi et al. instrument having a radius of curvature of 11.5 mm. (apparently intended to fit around a small eye) could be used on a large cornea, particularly since the radius of curvature of applicant's instrument can be as large as 12 mm. Contrary to applicant's remarks on page 10, it is not the Examiner's position that it would have been obvious to use the Yaacobi et al. instrument to separate the corneal surface epithelium from the underlying cornea. Rather, it is the Examiner's position that the Yaacobi et al. instrument is inherently capable of performing this function.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

mht  
6/14/06



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731